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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,554	02/04/2006	Jeroen Alphons Tonnaer	2003-793US	2808

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,554	TONNAER, JEROEN ALPHONS	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed March 1, 2011 have been received and entered into the application.

Response to Arguments

Applicant's arguments filed March 4, 2011 have been fully considered but they are not persuasive. Applicant argues that the '476 patent does not teach or suggest anything regarding a patient population in need of treatment of schizophrenia and having at least one of the comorbid conditions without increasing body mass index and the kit set forth in claim 7. This is not persuasive because '476 teaches a therapeutic benefit of asenapine in the treatment of schizophrenia in general while Aronne teaches that there is higher rate of schizophrenia patients comorbid with obesity compared to the general population. Aronne's definition of the term "overweight" overlaps with the patient population as defined in Applicants' claims. Accordingly, the schizophrenic patients disclosed by '476 patent are the subject population in need of protection against weight gain as taught by Aronne. It would have been obvious to one of ordinary skill in the art to employ asenapine for the treatment of schizophrenic patients comorbid with obesity because asenapine is effective in the treatment of schizophrenia which is a condition highly comorbid with obesity as well known in view of Aronne. One of ordinary

skill in the art would be motivated to employ asenapine in schizophrenic patients highly comorbid with obesity in order to achieve an expected therapeutic benefit of treating schizophrenia. One of ordinary skill in the art would immediately envision that the effectiveness of asenapine in the treatment of schizophrenia would be retained regardless of the patient's weight condition. With regard to mechanism of action of treating schizophrenia without increasing body mass index is obviously an unavoidable effect upon the administration of asenapine in schizophrenia patients in general who are highly comorbid with obesity. With regarding the kit including instructions set forth in claim 7, such is obvious because the '476 patent teaches asenapine is used by a human to treat schizophrenia, it would have been *prima facie* obvious to one of ordinary skill in the art to include instructions as to how to administer the contents of the article for that purpose. The instructions would differ from those recited in claims only in the wording of the instructions including the content which does not increase the body mass index. However, it is noted that the printed matter such as label in the instructions has no functional relation with the substrate on which it appears, it does not distinguish Applicants' claimed invention over that of '476 patent. *See In re Gulack*, 703 F.2d1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983). Hence, the article in a kit recited in claim 7 would have been *prima facie* obvious to one of ordinary skill in the art over the '476 patent. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S.Patent No. 5,763,476) of record in view of Aronne (2001) and further in view of Alexander-Bridges et al. (U.S.Patent No. 5,496,831).

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Delbressine et al. do not teach that the schizophrenic patient population disclosed by Delbressine et al. having BMI values and the population experienced weight gain while being treated with another antipsychotic agent set forth in claims 1, 8-11; mechanism of action of treating schizophrenia without increasing body mass index; and the kit.

Aronne teaches that the rate of patients with schizophrenia comorbid with obesity is higher compared to the general population (abstract). Aronne teaches the term "overweight" is defined as having a body mass index (BMI) of $\geq$ 25 (page 13 left-hand column first full paragraph).

Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight (kg) to the square of the height

(m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28. (column 5, lines 55-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Org 5222 (also known as asenapine maleate) to schizophrenic patients comorbid with obesity having a body mass index (BMI) of $\geq$ 25. One would have been motivated to make such a modification because in general, there is high rate of a patient with schizophrenia comorbid with obesity that is known to be defined as a patient having a BMI of $\geq$ 25 as taught by Aronne, and because Delbressine et al. teach that asenapine is useful for the treatment of schizophrenia in general. One would make such a modification in order to achieve a beneficial effect of asenapine in treatment of schizophrenia inclusive of those comorbid with obesity with the patient having a body mass of $\geq$ 25. There is a reasonable expectation of success in treatment of schizophrenia in a patient with overweight problems like obesity because the effectiveness of asenapine in treatment of schizophrenia would be retained regardless of their weight or the cause of the weight gain due to previous antipsychotic agent. With regard to schizophrenic patient population in need of protection against weight gain, such is obvious because the patient population having schizophrenia are generally comorbid with obesity as taught by Aronne et al. Therefore, the schizophrenic patients are generally in need of protection against weight gain.

With regard to schizophrenic patient population treated having BMI values set forth in claims 1, 10 and 11, such are obvious because Aronne teaches that patient who are over weight is defined as having BMI greater than or equal to 25 and Alexander-

Bridges et al. further teach that treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28 as well known. There is a lack of teaching in the specification that the BMI value in the applicants' population is critical. With regarding the limitation of a kit set forth in claim 7 such is obvious because given that the Delbressine et al teach that asenapine is for used by a human to treat schizophrenia, it would have been *prima facie* obvious to one of ordinary skill in the art to include instructions as to how to administer the contents of the article for that purpose. The instructions would differ from those recited in claim 7 only in the wording of the instructions including the content which does not increase the body mass index. However, it is noted that the printed matter such as label in the instructions has no functional relation with the substrate on which it appears, it does not distinguish Applicants' claimed invention over that of Delbressine et al. *See In re Gulack*, 703 F.2d1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983). Hence, the article in a kit recited in claim 7 would have been *prima facie* obvious to one of ordinary skill in the art over Delbressine et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
March 4, 2011